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510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date

May 29, 2013

Manufacturer

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AUG 2 9 2013

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Contact person: Mr. Dave Kim

Trade/Proprietary Name:

EzDent-i /E2 / ProraView

Common Name:

Dental Imaging Software

Classification Name:

System, image processing, radiological (21CFR 892.2050, Product code LLZ, Class2)

Description:

EzDent-i is a dental imaging software solution that stores, analyzes and diagnoses patient images that have been acquired through VATECH dental equipment.

EzDent-i is equipped with everything you need for digital panoramic and cephalometric image storage, processing and viewing. **EzDent-i** functions as a central storage point for digital images and associated patient data. Images can be acquired directly from equipment that **EzDent-i** currently supports. In addition, images can be imported from other digital sources.

The Main Functions of EzDent-i

With **EzDent-i** you can perform the following operations assuming that all the other equipment is ready to use.

1. Create and store new patient information in a database
2. Capture and store digital X-ray images with exposure values from the device.
3. Capture and store intraoral photographs.
4. Export and import digital images
5. Process images to enhance their diagnostic value with dental-specific tools
6. Analyze the image with application-specific measurement tools
7. Build an environment with multiple workstations using a database shared over a network.
8. Printing images and image related information.

EzDent-i can be used in a network environment. If **EzDent-i** is installed in several computers, the patient and image database can be shared among them and used from different workstations

Indication for use:

EzDent-i is dental imaging software that is intended to provide diagnostic tools for maxillofacial radiographic imaging. These tools are available to view and interpret a series of DICOM compliant dental radiology images and are meant to be used by trained medical professionals such as radiologist and dentist.

EzDent-i is intended for use as software to acquire, view and save 2D image files, load DICOM project files from panorama, cephalometric, and intra-oral imaging equipment.

Predicate Device:

Manufacturer : Gendex Dental System
Device : VixWin Pro
510(k) Number : K060178 (Decision Date – March 10, 2006)

Comparison of features and specifications of the device and SE device:

Characteristic	EzDent-i	VixWin Pro
510K number	K131594	K060178
Manufacturer	EWOO Soft	Gendex Dental System
Indications for use	EzDent-i is dental imaging software that is intended to provide diagnostic tools for maxillofacial radiographic imaging. These tools are available to view and interpret a series of DICOM compliant dental radiology images and are meant to be used by trained medical professionals such as radiologist and dentist. EzDent-i is intended for use as software to acquire, view and save 2D image files, load DICOM project files from panorama, cephalometric, and intra-oral imaging equipment.	VixWin Pro controls capture, display, treatment, analysis and saving of X-ray digital images from DenOptix®,Visualix®/GX-S, Orthoalix 9200 DPI and DDE digital imaging systems produced by Gendex. It can also handle other types of digital images, e.g. color images from an intraoral or extraoral dental camera, such as the Gendex Concept IV series, or images acquired by digitizing film with a flat bed scanner.
Platform	IBM-compatible PC or Mac	PC
Operating System	Microsoft Window 7, Window 8, Mac(Leopard, Snow Leopard, Lion)	Windows 98, 2000 and XP

User Interface	Mouse, Keyboard	Mouse, Keyboard
Image Input Sources	Images can be scanned, loaded from digital cameras or card readers, or imported from a radiographic imaging device	Images can be scanned, loaded from digital cameras or card readers, or imported from a radiographic imaging device
32 bit / 64 bit	32 / 64 bit	32 / 64 bit
Image format	DICOM	DICOM
Patient Database Compatibility	SQL	SQL
Includes Image Measurement tools	Linear distance, angle	Angle, length measurement
Image viewing	Full, side by side, gallery, thumbnail	Full, side by side, gallery, thumbnail
Image manipulation	Brightness, contrast, sharpness, inverse, film view, rotate, zooming, whitening, nerve canal tracing, memo	Sharpen, smooth, area measurement, rotate, flip, mirror, reverse, grayscale enhance, emboss, brightness, contrast, equalize, contrast, emboss, despeckle, optimizer, colorize, magnify, spotlight, annotation, soft tissue filter- for cephalometric only,
Implant module	Generic implant libraries	Include implant libraries from Nobel Biocare, Bicon, 3i, and Straumann, and generic
3D imaging capability	Includes interface to 3D imaging software, Ez3D-i. EzDent-i imaging software does not view, transfer or process 3D radiographs.	Includes interface to 3D imaging software provided with Gendex GXDP-700 series, GXCB-500series. VixWin imaging software does not view, transfer or process 3D radiographs.
Image annotation	Text, paint, ellipse, pointer, select, draw, magnify, line, rectangle, polygon, ruler, protractor, smile library, smudge, brush, redeye reduction, select region, copy / paste	Select Mark, Hollow Rectangle, Straight Line, Attach a Note, Freehand Line, Hollow Ellipse, Hollow Polygon, Polyline, Length Measurement, Filled rectangle, Highlighter, text, text Stamp, Arrow, Filled Ellipse, Filled Polygon, Hide/Show Marks, Angle

Substantial Equivalence:

The subject device and predicate device are substantially equivalent in terms of 2D image

diagnostic analysis, having the similar indications for use and functionalities like functions to sort and save DICOM files and 2D image files from different modality [Panorama, cephalometric, intraoral]. Both are compatible with similar operation software and offer similar image viewing, annotation and simulation features. Both EzDent-i, the proposed device, and VixWin Pro, the predicate device are categorized in product code LLZ; equivalence between these models is evident.

EzDent-i radiographic imaging viewer is similar to the predicate device and the proposed device does not raise any new or potential safety risks to the user or patient and questions of safety or effectiveness. The proposed device is equivalent in performance to existing legally marketed devices.

Technological Characteristics:

EzDent-i is a software device that does not contact the patient, nor does it control any life sustaining devices. Results produced by the software's diagnostic, treatment planning and simulation tools are dependent on the interpretation of trained and licensed radiologists, clinicians and referring physicians as an adjunctive to standard radiology practices for diagnosis. A physician, providing ample opportunity for competent human intervention interprets images and information being presented.

Nonclinical Testing:

The complete system configuration has been assessed and tested by the manufacturer and passed all in-house testing criteria. The software validation test was designed to evaluate all input functions, output functions, and actions performed by EzDent-i. Each operational mode and the process followed are documented in the Software Validation Report.

The validation testing verified and validated the risk analysis and individual performance results were within the predetermined acceptance criteria.

Safety and Performance Data:

- IEC 62304 Medical device software – Software life-cycle processes : 2006
- ISO 14971 Medical Devices – Application of risk management to medical device : 2007

Conclusion:

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The premarket notification for EzDent-i contains adequate information and data to determine substantial equivalence to the predicate device. The new device and predicate device are substantially equivalent in the areas of technical characteristics, general function, application, and intended use. The new device does not introduce a fundamentally new scientific technology and the nonclinical tests demonstrate that the device is safe and effective. Therefore, it is our opinion that the EzDent-i described in this submission is substantially equivalent to the predicate device.

END

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 29, 2013

Ewoo Soft Co., Ltd.
% Mr. Dave Kim
Medical Device Regulatory Affairs
Mtech Group
12946 Kimberley Lane
HOUSTON TX 77079

Re: K131594
Trade/Device Name: EzDent-i /E2/ProraView
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: August 09, 2013
Received: August 13, 2013

Dear Mr. Kim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

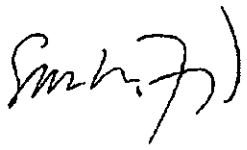
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131594

Device Name: EzDent-i / E2 / Prora View

Indications for Use:

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Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health

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